



Complete Summary

GUIDELINE TITLE

Metabolic syndrome.

BIBLIOGRAPHIC SOURCE(S)

Finnish Medical Society Duodecim. Metabolic syndrome. In: EBM Guidelines. Evidence-Based Medicine [CD-ROM]. Helsinki, Finland: Duodecim Medical Publications Ltd.; 2005 Sep 9 [Various].

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Finnish Medical Society Duodecim. Metabolic syndrome (MBS). In: EBM Guidelines. Evidence-Based Medicine [CD-ROM]. Helsinki, Finland: Duodecim Medical Publications Ltd; 2004 Jun 29. various p.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

On January 5, 2006, GlaxoSmithKline and the U.S. Food and Drug Administration (FDA) notified healthcare professionals about post-marketing reports of new onset and worsening diabetic macular edema for patients receiving rosiglitazone. In the majority of these cases, the patients also reported concurrent peripheral edema. In some cases, the macular edema resolved or improved following discontinuation of therapy and in one case, macular edema resolved after dose reduction. See the [FDA Web site](#) for more information regarding rosiglitazone.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

SCOPE

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

SCOPE

DISEASE/CONDITION(S)

Metabolic syndrome (MBS)

Conditions that may be associated with MBS, such as

- Type 2 diabetes
- Cardiovascular disease
- Alzheimer's disease

GUIDELINE CATEGORY

Diagnosis
Management
Prevention
Treatment

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Internal Medicine

INTENDED USERS

Health Care Providers
Physicians

GUIDELINE OBJECTIVE(S)

Evidence-Based Medicine Guidelines collect, summarize, and update the core clinical knowledge essential in general practice. The guidelines also describe the scientific evidence underlying the given recommendations.

TARGET POPULATION

Patients with suspected or known metabolic syndrome (MBS)

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Waist circumference

2. Fasting serum triglyceride level
3. Fasting serum high-density lipoprotein cholesterol level
4. Blood pressure
5. Fasting plasma glucose level
6. Oral glucose tolerance test
7. Consideration of other important signs/clinical findings supporting diagnosis including familial component, obesity, abnormal glucose tolerance test result, hyperuricaemia, microalbuminuria, hyperinsulinaemia

Treatment/Secondary Prevention

Non-pharmacologic

1. Physical activity
2. Weight reduction
3. Change in eating habits
4. Smoking cessation
5. Limiting alcohol consumption

Drug Treatment

1. Low-dose aspirin, unless contraindicated
2. Management of individual components of metabolic syndrome
 - Highly selective beta-blockers, angiotensin-converting enzyme (ACE) inhibitors, alpha 1 receptor blockers, calcium channel blockers, and angiotensin II receptor antagonists for hypertension
 - Statins for dyslipidaemia
 - Fibrates for hypertriglyceridaemia
 - Metformin or thiazolidine derivatives or insulin for dysglycaemia
 - Biguanides, acarbose, and guar gum for type 2 diabetes
 - Orlistat, sibutramine, or endocannabinoid-receptor blockers to lower weight and reduce fat

Management

1. Physician follow-up for patients on drug therapy
2. Practice nurse follow-up for patients not on drug therapy with physician consultation, if applicable

MAJOR OUTCOMES CONSIDERED

Rate of type 2 diabetes, cardiovascular disease, and Alzheimer's disease

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
 Hand-searches of Published Literature (Secondary Sources)
 Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The evidence reviewed was collected from the Cochrane database of systematic reviews and the Database of Abstracts of Reviews of Effectiveness (DARE). In addition, the Cochrane Library and medical journals were searched specifically for original publications.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

- A. Strong research-based evidence. Multiple relevant, high-quality scientific studies with homogenic results.
- B. Moderate research-based evidence. At least one relevant, high-quality study or multiple adequate studies.
- C. Limited research-based evidence. At least one adequate scientific study.
- D. No research-based evidence. Expert panel evaluation of other information.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The levels of evidence [A-D] supporting the recommendations are defined at the end of the "Major Recommendations" field.

The Aim

- Primary and secondary prevention of type 2 diabetes, cardiovascular disease (hypertension, coronary heart disease, stroke, intermittent claudication), and possibly also Alzheimer's disease

Definition of Metabolic Syndrome (MBS)

- MBS is a clustering of risk factors for type 2 diabetes and cardiovascular diseases. The risk factors are associated with obesity, insulin resistance, endothelial dysfunction and possibly with cellular membrane disruption (Reaven, 1988; Laakso, 1993).
- The clustering of risk factors results in a higher risk of type 2 diabetes and cardiovascular disease than would be estimated if each individual factor were taken into account separately (Tuomilehto et al., 2001; McNeil et al., 2005) Insulin resistance associated with obesity, plays an important role in the accumulation of the components of MBS in any one individual.
- In insulin resistance, the biological response to insulin is impaired in the adipose tissues, muscles, the liver, and possibly the brain. The core abnormality of the syndrome includes the clustering of insulin resistance, compensatory hyperinsulinaemia, and dyslipidaemia in an obese hypertensive.
- MBS is usually evident from truncal obesity which can be detected in clinical practice by measuring the circumference of the waist. MBS is rare in slim individuals.
- The presence of MBS may be detected through medical history, anthropometry, blood pressure readings and by measuring
 - Lipid values
 - Blood or plasma glucose (glucose tolerance test or postprandial glucose if fasting glucose is normal).

The Diagnosis of MBS

- According to the International Diabetes Federation (IDF) consensus 2005, the diagnostic criteria of MBS are:
 1. Central obesity, defined as waist circumference of ≥ 94 cm for European men and ≥ 80 cm for European women PLUS
 2. At least two of the following factors:

1. Raised serum triglyceride level: fasting value ≥ 1.70 mmol/L, or specific treatment for this lipid abnormality
 2. Reduced serum high-density lipoprotein (HDL)-cholesterol: fasting value < 1.03 mmol/L in males and < 1.29 mmol/L in females, or specific treatment for this lipid abnormality
 3. Raised blood pressure (BP): systolic BP ≥ 130 mmHg or diastolic BP ≥ 85 mmHg, or treatment of previously diagnosed hypertension
 4. Raised fasting plasma glucose: ≥ 5.6 mmol/L, or previously diagnosed type 2 diabetes. If the value is above 5.6 mmol/L, oral glucose tolerance test is strongly recommended but is not necessary to define the presence of the syndrome.
- Other important signs and clinical findings supporting the diagnosis include:
 - Familial component: first-degree relative with type 2 diabetes
 - Obesity: body-mass-index (BMI) ≥ 30 kg/m². For calculation see programme 1 included in the original guideline document.
 - Abnormal glucose tolerance test result: impaired glucose tolerance (IGT) or type 2 diabetes (NIDDM= non-insulin-dependent diabetes mellitus) according to World Health Organization [WHO] criteria)
 - Hyperuricaemia: fasting serum urate ≥ 450 micromoles/L in men, ≥ 340 micromoles/L in women
 - Microalbuminuria: urine albumin ≥ 20 milligrams/24 hours
 - Hyperinsulinaemia: fasting plasma insulin ≥ 78 pmol/L (≥ 13.0 mU/L)
 - Alzheimer's disease, depression, and sleep apnoea may also be associated with MBS.

Prevalence

- Depending on the different definitions of MBS, its prevalence in a middle-aged population varies between 17% and 30% for men and between 8% and 20% in women (Alexander et al., 2003).
- About one half of hypertensive patients are hyperinsulinaemic and/or have insulin resistance (Reaven, Lithell, & Landsberg, 1989). 35% of hypertensive Finnish men and 25% of hypertensive Finnish women fulfill the criteria for MBS.
- Among subjects with central obesity (having both BMI ≥ 30 kg/m² and waist circumference > 100 cm in men and > 90 cm in women), the prevalence of MBS is about 55% in men and 40% in women. In the non-obese subjects without central adiposity the prevalence of MBS is 2 to 4%.

Treatment

- The treatment is principally non-pharmacological and based on lifestyle changes. This approach has been shown to have an excellent effect, for example in the prevention of diabetes (DPS Study) (Tuomilehto et al., 2001; Knowler et al., 2002) [A].
- Lifestyle changes are the only treatment form which have an effect on all the components of MBS, and not employing this treatment should be considered ethically wrong.

Non-Pharmacological Treatment

- Increasing physical activity
- Weight reduction
- Dietary changes: increased intake of fibre and decreased intake of fat (particularly saturated fat) and rapidly metabolized carbohydrates (highly refined)
- Cessation of smoking
- Limit alcohol intake to a moderate level

Drug Treatment

- Drug treatment encompassing the entire MBS does not exist, and treatment should therefore consist of the management of the individual components of the syndrome.
- Unless contraindicated, all patients with MBS should be prescribed low dose aspirin.
- The treatment of hypertension in a patient with MBS should not contain drugs that worsen insulin resistance, such as non-selective beta-blockers and high-dose diuretics, unless other reasons (secondary prevention of myocardial infarction) warrant their use. The first-line drugs for the treatment of hypertension are:
 - Angiotensin-converting enzyme (ACE) inhibitors
 - Angiotensin-II receptor antagonists (losartan, valsartan, eprosartan, candesartan)
 - Alpha1 receptor blockers
 - Calcium-channel blockers
 - Highly selective beta-blockers
- Dyslipidaemia in a patient with MBS should principally be treated with statins bearing in mind that the patient has a high risk of coronary artery disease.
- Hypertriglyceridaemia should be treated with fibrates if, in spite of non-pharmacological treatment, the triglyceride values are persistently >5.0 mmol/L. Hypertriglyceridaemia in a patient with MBS should be treated medically (statin or fibrate) if the level of triglycerides is >2.30 mmol/L and total-cholesterol/HDL-cholesterol ratio is higher than 5 or if HDL-cholesterol is lower than 0.9 mmol/L.
- Dysglycaemia in a patient with MBS should be treated with metformin or thiazolidine derivatives (pioglitazone or rosiglitazone) since these will not only improve the dysglycaemia but will also have an effect on the other components of the MBS. Insulin may also be used for the treatment of dysglycaemia in a MBS patient to achieve good diabetic control.
- Biguanides, acarbose, and guar gum may correct insulin resistance and are thus feasible as a first-line drug for an obese patient with type 2 diabetes.
- Orlistat may be indicated in MBS if the BMI is >30 kg/m². Orlistat is an anti-obesity drug and it reduces the amount of visceral fat, in particular. Sibutramine may be used as an alternative. However, the new endocannabinoid-receptor blockers are likely to be of most benefit. Rimobabant is an example of these yet to be marketed anti-obesity drugs, and it has a positive effect on almost all the components of MBS.

Follow-up of a Patient with MBS

- Motivation and monitoring of lifestyle changes is of the utmost importance.

- The monitoring of a patient who requires drug treatment is the responsibility of a doctor. Regular appointments may often act as an important motivator.
- The monitoring of a patient who does not require drug treatment may be carried out by a practice nurse. The following should be included in the follow-up: motivation of lifestyle changes, weight and waist circumference measurements, blood pressure readings, and checking of blood lipids and fasting blood glucose. A doctor should be consulted if:
 - Blood pressure repeatedly >140 mmHg and/or >90 mmHg
 - Total cholesterol: HDL-cholesterol ratio >5
 - Triglyceride values repeatedly ≥ 2.30 mmol/L
 - Plasma glucose is ≥ 7.8 mmol/L (fasting plasma glucose is ≥ 6.7 mmol/L)
 - The patient develops symptoms of another illness (gout, etc.)

Definitions:

Levels of Evidence

- Strong research-based evidence. Multiple relevant, high-quality scientific studies with homogenic results.
- Moderate research-based evidence. At least one relevant, high-quality study or multiple adequate studies.
- Limited research-based evidence. At least one adequate scientific study.
- No research-based evidence. Expert panel evaluation of other information.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

[References open in a new window](#)

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Concise summaries of scientific evidence attached to the individual guidelines are the unique feature of the Evidence-Based Medicine Guidelines. The evidence summaries allow the clinician to judge how well-founded the treatment recommendations are. The type of supporting evidence is identified and graded for select recommendations (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Appropriate diagnosis and treatment of the metabolic syndrome
- The aim for treating metabolic syndrome (MBS) is for the primary and secondary prevention of type 2 diabetes, cardiovascular disease

(hypertension, coronary heart disease, stroke, claudication), and Alzheimer's disease

POTENTIAL HARMS

If a hypertensive has metabolic syndrome, it is important to avoid non-selective beta-blockers and high-dose diuretics, as these drugs may worsen insulin resistance.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Resources

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Jun 29 (revised 2005 Sep 9)

GUIDELINE DEVELOPER(S)

Finnish Medical Society Duodecim - Professional Association

SOURCE(S) OF FUNDING

Finnish Medical Society Duodecim

GUIDELINE COMMITTEE

Editorial Team of EBM Guidelines

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Author: Mauno Vanhala

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

This guideline is included in a CD-ROM titled "EBM Guidelines. Evidence-Based Medicine" available from Duodecim Medical Publications, Ltd, PO Box 713, 00101 Helsinki, Finland; e-mail: info@ebm-guidelines.com; Web site: www.ebm-guidelines.com.

AVAILABILITY OF COMPANION DOCUMENTS

A body mass index (BMI) calculator is available in the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on August 30, 2005. This summary was updated by ECRI on October 27, 2005. This summary was updated by ECRI

on January 11, 2006 following the U.S. Food and Drug Administration advisory on rosiglitazone.

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Date Modified: 10/9/2006

